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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,567	09/05/2006	Joern Borgert	DE040071US1	7279

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PHILIPS INTELLECTUAL PROPERTY & STANDARDS
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EXAMINER	
GUPTA, VANI	
ART UNIT	PAPER NUMBER
3777	

NOTIFICATION DATE	DELIVERY MODE
05/11/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/598,567	BORGERT ET AL.	
	Examiner	Art Unit	
	VANI GUPTA	3777	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 5-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 5-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. ***Claims 1, 5, 6, 8, 10, 11, 12, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cragg et al. (US 6,146,373) in view of Eick et al. (US 6,955,674 B2).***

Regarding Claim 1, *Cragg et al.* (hereinafter *Cragg)* discloses a catheter apparatus for therapy, such as therapeutic occlusion of an area of a heart, the catheter apparatus comprising:

a. a catheter ***(figs. 1 and 2, (10))*** configured to inject a filling or plugging material an aneurysm *(col. 4, line 25 – col. 5, line 7)*;

b. an active locator attached to the catheter ***(fig. 6, (50) and (52))*** and configured to provide coordinates to determine spatial position and orientation of the catheter *(col. 9, ll. 40 – 50);* and

c. a pump configured to controllably supply filling material to the catheter *(col. 6, ll. 24 – 31).*

However, Cragg differs from Claim 1 in that Cragg does not disclose specifically a monitor connected to the active locator and the pump, wherein the monitor is configured to monitor the spatial position and/or orientation of the catheter to detect emergence of the catheter from the aneurysm during the injection of the drug into the aneurysm, and configured to stop the supply of the drug in response to the detected emergence.

Nonetheless, *Eick et al.* (hereinafter *Eick*) suggests a system for tracking the position of the catheter relative to the treatment sight by monitoring the x-axis of the coordinate system that the catheter is tracked within. When there is a change in position along the X-axis such that the change in position is higher than an allowed limit, the catheter is considered "dislocated" *(col. 3, line 65 – col. 4, line 27)*, and "terminates" treatment upon dislocation *(col. 6, ll. 25 – 27).*

Accordingly, it would have been obvious to one of ordinary skill in the art, having the teachings of Cragg and Eick before one *at the time the invention was made*, to modify the embolization-treatment-of-aneurysms device and method teachings of Cragg with the catheter-dislocation-monitoring-and treatment-termination-method teachings of Eick so that one could ensure that only the targeted region is treated and surrounding healthy tissue is not damaged *(Eick: col. 1, ll. 55 – 58).*

Regarding claims 5 and 8, Cragg in view of Eick suggests a catheter, a pump device and an electromagnetic locating device, and monitoring capabilities for monitoring the spatial position and/or orientation of the catheter based on the provided coordinates from the locator for detecting emergence of the catheter from the region of interest during injection of the filling material into the aneurysm, and thereupon stopping the supply of the drug *(please see rejections of Claim 1).*

Regarding Claim 6, Eick suggests a control circuitry ("LocaLisa system" and "microprocessor") containing storage space for storing ("collecting") a "road map" and is designed to record measured position and/orientation data ("x-y-z coordinates) from the locator (see rejection of Claim 1) using the road map *(col. 6, ll. 25 – 63).* Applicant should note that control circuitry *(or "LocaLisa" system - col. 1, ll. 15 – 20)* comprises a computer, which would

inherently comprise a storage device capable of storing any type of information, including a road map.

Regarding Claim 10, Cragg teaches that the plugging material can comprise a curable polymer material, plastic beads, a plastic coil, a hydrogel and/or a fibrin sponge, as is known in the art *(col. 1, ll. 25 – 33).*

Regarding Claim 11, please refer to rejections of claims 1 and 5.

Regarding Claim 12, Eick teaches that the position of the locator is recorded using a road map of locator positions, the detecting of the emergence of the catheter from the aneurysm further being based on the road map *(see rejection of Claim 6).*

Regarding Claim 14, Cragg in view of Eick teaches that the navigation of the catheter in the vascular system is assisted by determining the position of the active locator, as discussed in the rejection of Claim 11.

2. *Claims 2, 7, 9 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cragg is view of Eick as applied to claims 1 and 5 above and further in view of Kucharczyk et al. (US 6,463, 317 B1).*

Regarding claim 2, Cragg in view of Eick teaches each and every limitation of the claim, as discussed above in reference to claim 1.

However, Cragg in view of Eick does not teach the catheter apparatus, wherein the active locator comprises a magnetic field sensor.

Nonetheless, *Kucharczyk et al.* (hereinafter *Kucharczyk*) teaches an aneurysm treatment device that comprises a magnetic field sensor for tracking the position of the catheter. Moreover,

Kucharczyk suggests that it is known in the art to use magnetic-field based sensors for tracking positions of catheters *(col. 4, ll. 43 – 67)*.

Accordingly, it would have been obvious to one of ordinary skill in the art, having the teachings of Cragg and Eick, and Kucharczyk before one *at the time the invention was made*, to modify the aneurysm device and method teachings of Cragg and Eick with the magnetic-field based sensors for tracking positions of aneurysm-treatment-catheter teachings of Kucharczyk so that one could visualize the catheter during treatment using magnetic resonance imaging, if so required *(Kucharczyk: col. 10, ll. 21 – 24)*.

Regarding Claim 7, Kucharczyk suggests that the apparatus of Claim 5 further comprises an X-ray imaging device *(col. 9, ll. 37 – 38)*.

Regarding Claim 9, Applicant should note that it would be inherent matter of design choice that if Cragg in view of Eick further in view of Kucharczyk discusses a locating device that works in conjunction with a magnetic field sensor device *(rejection of Claim 2)*, then the locating device would comprise capabilities for generating an electromagnetic field for the magnetic field sensor to sense. The generation of an electromagnetic field that is spatially and/or temporally inhomogeneous is commonplace, as is known in the art.

Regarding Claim 13, Kucharczyk suggests that the catheter and the region of interest - such as an aneurysm – are imaged together at the start of embolization, preferably by means of X-rays or with administration of a contrast agent *(col. 10, line 18; col. 13, ll. 25 – 30)*.

Response to Arguments

3. Applicant's arguments, see page 6, filed March 29, 2011, with respect to claims 6 and 13 have been fully considered and are persuasive. The 35 U.S.C. 112 second paragraph rejections of these have been withdrawn.

4. Applicant's arguments filed March 29, 2011 with respect to the art rejections of the present claims have been fully considered but they are not persuasive.

In response to applicant's argument that in Eick, "[there is a] method uses an externally applied electrical field that is detected via standard catheter electrodes. Three skin-electrode pairs are used to send three small, 1.0 mA currents through the thorax in three orthogonal directions, with slightly different frequencies of 30 kHz used for each direction. The resulting voltage can be recorded via standard catheter electrodes and be used to determine electrode position," and therefore does not teach the features in question; the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Furthermore, there is nothing in this passage of Eick that would suggest that the electrode is not an "active locator," as presented in the claim. Applicant is reminded that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). If the active locator is configured in a way that is different than Eick's, and therefore is novel over the prior art, then the applicant must present it in the claim(s).

Furthermore, in response to applicant's arguments against the references individually (on page 8), one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant's arguments with respect to Kucharczyk are moot in light of above responses.

Conclusion

5. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VANI GUPTA whose telephone number is (571)270-5042. The examiner can normally be reached on Monday - Thursday (8:30 am - 6:00 pm; EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert (Tse) Chen can be reached on 571-272-3672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/V. G./
Examiner, Art Unit 3777

/Tse Chen/
Supervisory Patent Examiner, Art Unit 3777